

MAUDE Search

BRAND NAME	UNK
TYPE OF DEVICE	LATEX GLOVE
MANUFACTURER	SAFESKIN CORP. 12671 HIGH BLUFF DR. SAN DIEGO, CA 92130 US 114054
DEVICE EVENT KEY	114054
MDR REPORT KEY	116243
EVENT KEY	109328
REPORT NUMBER	2084395-1997-00027
510(K) NUMBER	K861426
PRODUCT CODE	LYY
REPORT SOURCE	MANUFACTURER
WAS MANUFACTURER REPORT SUBMITTED?	YES
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	26-AUG-1997
IS THIS AN ADVERSE EVENT REPORT?	NO
OUTCOME OF EVENT	LAWSUIT
DEVICE EXPIRATION DATE	NA
DEVICE MODEL NUMBER	UNK
DEVICE CATALOGUE NUMBER	UNK
DEVICE LOT NUMBER	UNK
OTHER DEVICE ID NUMBER	NA
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
IS THE REPORTER A HEALTH PROFESSIONAL?	NO
TYPE OF REPORT	FOLLOWUP
REPORT DATE	05-Aug-1997
WAS THE REPORT SENT TO FDA?	NO
INITIAL REPORT SOURCE	ATTORNEY
DATE MANUFACTURER RECEIVED	12-JUN-1997
MANUFACTURER REPORT NO	2084395-1997-00027
EVENT REPORT TYPE	DEATH
WAS DEVICE EVALUATED BY MANUFACTURER?	D
MANUFACTURE DEVICE DATE	UNK
LABELED FOR SINGLE USE?	YES

TYPE OF DEVICE USAGE

UNKNOWN

EVENT DESCRIPTION

ON 10/20/1998, SAFESKIN CORP WAS SERVED WITH THE FOLLOWING LAWSUIT: LAWSUIT ALLEGED THAT THE DECEDENT WAS EXPOSED TO LATEX PRODUCTS INCLUDING LATEX GLOVES. AS A PROXIMATE RESULT, THE INDIVIDUAL DEVELOPED SERIOUS ILLNESSES AND INJURIES WHICH ULTIMATELY LEAD TO HIS DEATH ON 8/29/1997.

ADDITIONAL MANUFACTURER NARRATIVE

DISCLAIMER: SAFESKIN CORP (SAFESKIN) SUBMITS THE FOLLOWING REPORT TO THE FDA IN COMPLIANCE WITH 21 CFR 803. THIS REPORT IS BASED UPON INFO PROVIDED FROM A LAWSUIT IN WHICH SAFESKIN IS NAMED DEFENDANT. THIS REPORT SHALL NOT BE CONTRUED AS AN ADMISSION BY SAFESKIN THAT THE PRODUCT(S) DESCRIBED HEREIN ARE PRODUCTS OF ITS MFR AND ARE OR WERE DEFECTIVE OR DANGEROUS IN ANY RESPECT, OR THAT ANY CASUAL RELATIONSHIP EXISTS BETWEEN THESE PRODUCTS AND ANY ACTUAL OR POTENTIAL INJURY. IN ADDITION, THE SUBMISSION OF A REPORT BY SAFESKIN SHALL NOT BE CONSTRUED AS AN ADMISSION THAT A REPORTABLE EVENT HAS IN FACT OCCURRED.

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